

REMARKS

I. Claim Status

Claims 61-67 and 71-119 are currently pending. Claims 92-96 have been amended herein. Those amendments are supported in the specification and claims as originally filed and simply seek to correct inadvertent typographical errors. Accordingly, no new matter is added herein. Claims 61-119 stand rejected.

II. Indefiniteness Rejections

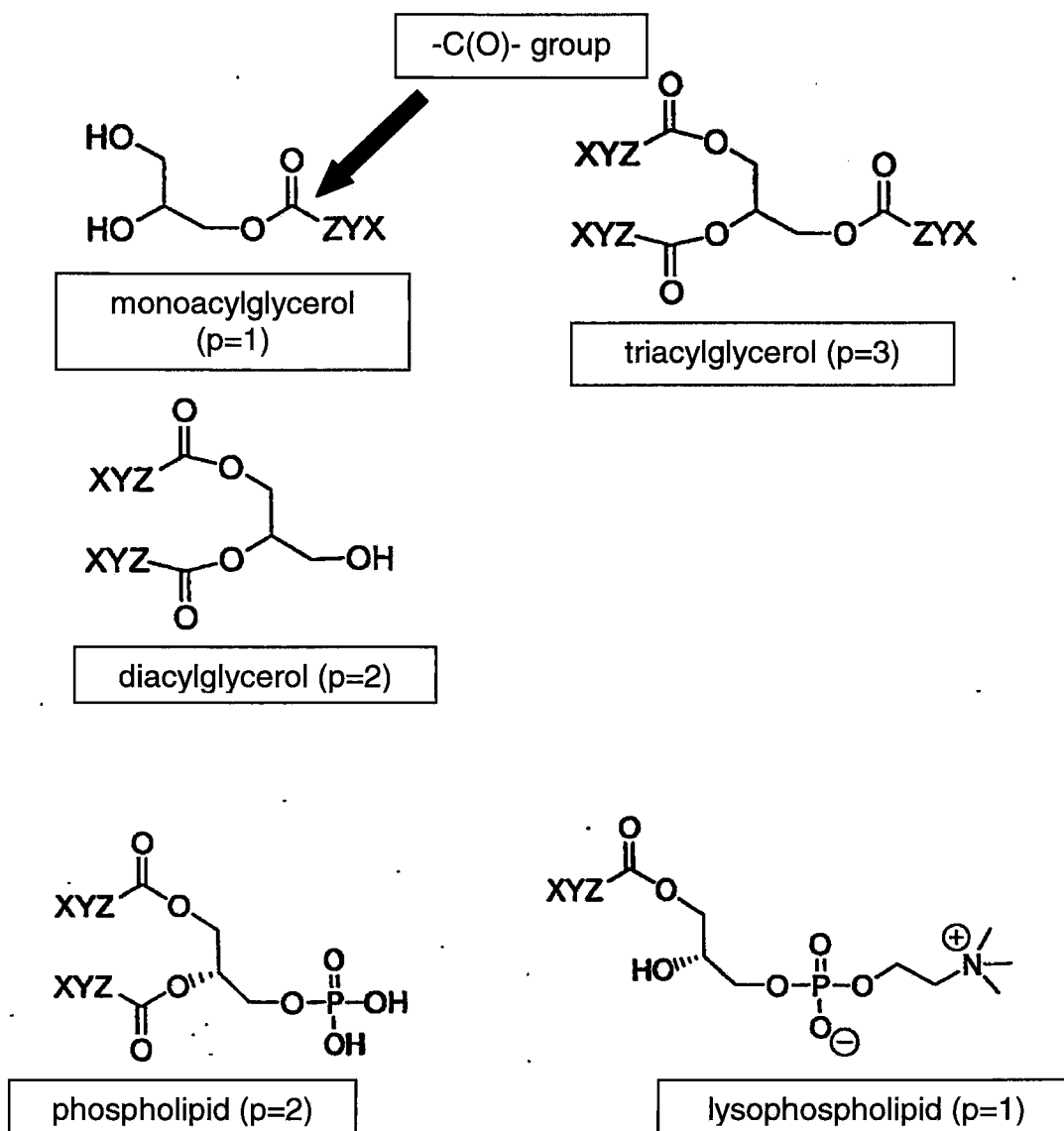
35 U.S.C. § 112, Second Paragraph Rejection of claims 1-119

The Examiner rejected claims 1-119 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Office Action dated July 13, 2009 (“Office Action”) at 2. Applicants respectfully traverse.

As an initial matter, Applicants point out that claims 1-60 and 68-70 have been canceled previously without prejudice. Thus, for the purposes of these remarks, Applicants focus only on the currently pending claims.

The Examiner concluded that the structure of the claimed compounds (see claim 61) “is still indefinite since it is unclear how the PHG groups are bound to the XYZ-C(O) group.” *Id.* However, one of ordinary skill in the art would be able to clearly identify the metes and bounds of the presently pending claims in view of the ample support found in the specification and based on his own knowledge of basic chemical principles. In particular, the specification is replete with examples of how the recited polar head groups (PHGs)—phospholipid, lysophospholipid, monoacylglycerol, diacylglycerol, and triacylglycerol—are to be bound to the rest of the presently claimed compounds. In fact, an example of the exact formula (I) that is presently being claimed is expressly provided for at p. 19, line 25. Additionally, possible head groups and their potential p values are

given beginning on p. 19, line 30 through the table on p. 20. The specification also provides specific examples of each type of PHG and examples of how they bind to the carbonyl carbon of the lipid group (XYZ-C(O)-), namely that an oxygen of the PHG forms an ester with the -C(O)- group of the lipid chain. See Specification at pp. 20-21 for representative examples of the recited polar head groups (a few examples duplicated here with headings for the Examiner's convenience).



One of skill in the art applies a basic understanding of chemical principles, and based on those and other examples throughout the specification, would have no doubt about the scope of the presently pending claims.

Finally, the Examiner should not reject chemical structures as indefinite unless the structures are clearly erroneous. *See* M.P.E.P. §2173.05(t) ("These structures should not be considered indefinite nor speculative in the absence of evidence that the assigned formula is in error.") The presently recited chemical structures have no clear error. It is well known in the art how PHGs can be chemically bonded to lipid chains, e.g., via the carbonyl carbon atom. Thus, the Examiner should withdraw this rejection and acknowledge that the claims are definite.

The Examiner continued to maintain the position that "it is unclear how p can be 3 in the case of where PHG is defined as phospholipid or a lysophospholipid, where, in those cases, at least 1 -OH group would be occupied by a phosphate group." Office Action at 2. Based on the discussion and examples provided above, one of ordinary skill in the art would recognize the very limitation that the Examiner points out. The claims do not require that p must be able to be 3 for all possible PHGs, claim 61 simply recites that "p is 1 to 3," i.e., p is any one of 1, 2, or 3. Here again, there is no clear error in the recited structure. *See* M.P.E.P. §2173.05(t). Thus, the presently pending claims are definite, and this rejection should be withdrawn.

The Examiner also rejected claims 92-96 for lacking antecedent basis to claim 87. Applicants have amended those claims to correct the inadvertent typographical errors. The present amendments render the rejection moot. Accordingly, it should be withdrawn.

III. Written Description Rejection

35 U.S.C. § 112, First Paragraph Rejection of Claims 61-82, 84-96, 98-101, and 116-119

The Examiner rejected claims 61-82, 84-96, 98-101, and 116-119 under 35 U.S.C. § 112, second paragraph as allegedly failing to comply with the written description requirement. Office Action at 3. Applicants respectfully traverse this rejection.

The Examiner stated that “the specification does not include this sub-genus of compounds and thus the specification does not show that the inventor were [*sic*] in possession of this sub-genus.” Office Action at 4. Applicants respectfully disagree—the specification does include a description, albeit not *in haec verba*, of the presently claimed subgenus. As mentioned above, the presently recited formula (I) is expressly disclosed at p. 19, line 25. Right above that formula, Z is defined, and it can be and in at least one embodiment, preferably, a C₁-C₆ alkyl group. Specification, p. 19, line 8. Y can be S, and is actually a highly preferred embodiment (p. 18, line 9), and PHG can be a phosphatidylethanolamine group or a phosphatidylethanolamine lysophospholipid group (p. 20, table). Thus, formula (I) where Z is a C₁-C₆ alkyl group is disclosed as is all of the other aspects of the objected to proviso.

The written description requirement does not require that the claims be recited *in haec verba* in the specification, it only requires that the claim limitations be supported through “express, implicit, or inherent disclosure.” M.P.E.P. §2163. As put forward herein, the specification does expressly provide the components of the proviso, and

implicitly contemplates the sub-genus presently claimed. Therefore, this rejection should be withdrawn

IV. 102(b) Rejections

Rejection over Ruoxin

The Examiner has rejected claims 61-64, 67, 84, and 86 under 35 U.S.C. § 102(b) as allegedly being anticipated by Ruoxin et al. *J. Org. Chem.* (1993) 58:1952-1954 ("Ruoxin"). Office Action at 4. Applicants respectfully traverse.

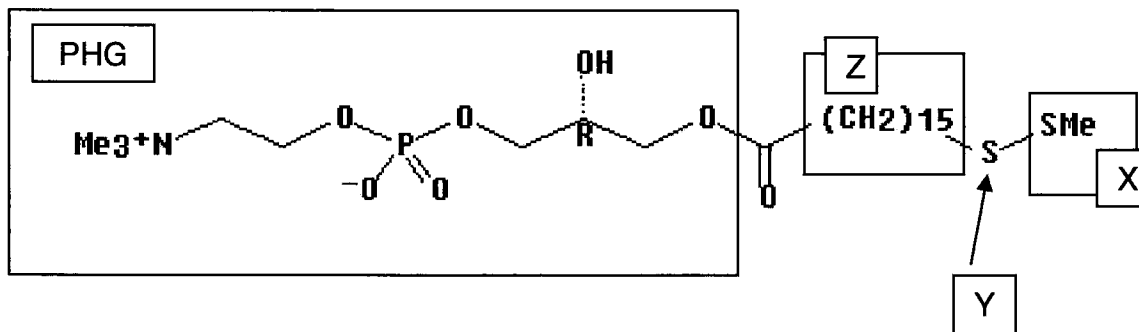
The Examiner cited to compound 11 of Ruoxin as allegedly anticipating the rejected claims, stating that the PHG is a phosphatidylcholine and is outside the scope of the proviso. *Id.* Applicants respectfully disagree because Ruoxin does not disclose a phosphatidyl choline. Instead, only phosphatidylethanolamines are disclosed and as such are not anticipatory of the presently pending claims.

Choline corresponds to the chemical formula: $[(CH_3)_3N^+CH_2CH_2OH]X^-$, wherein X is some counterion. The compounds in Ruoxin do not include the three methyl groups attached to the nitrogen atom. Instead, they include the protonated ethanolamine moiety ($H_3N^+CH_2CH_2O^-$) attached to the phosphorus. Thus, Ruoxin does not anticipate the presently pending claims, and this rejection should be withdrawn.

Rejection over Runquist

The Examiner rejected claims 65, 66, 80, and 81 under 35 U.S.C. § 102(b) as allegedly anticipated by Runquist et al., *Biochimica et Biophysica Acta, Biomembranes* (1988) 940(1):10-12 ("Runquist"). Office Action at 6. Applicants respectfully traverse this rejection.

In support of the rejection, the Examiner points out that Runquist teaches the following compound:



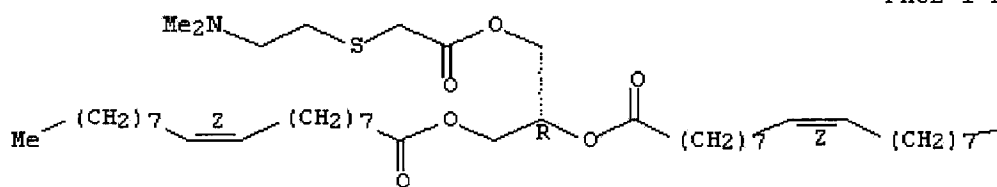
Applicants respectfully point out that the Runquist compound does not anticipate the present claims because the moieties of the Runquist compound do not fall within the scope of the presently recited claim limitations. For the purposes of highlighting the differences between the Runquist compound and the compounds presently claimed, Applicants have indicated which parts of the Runquist compound, above, would have to correspond to PHG, X, Y, and Z. X can be “a C₆-C₂₄ alkyl, all optionally substituted with at least one of F, hydroxy, C₁-C₄ alkoxy, C₁-C₄ alkylthio, C₂-C₅ acyloxy, and C₁-C₄ alkyl.” See claim 61. That definition does not include the -SMe group of the Runquist compound. An -SMe group is an alkylthio group and not a C₆-C₂₄ alkyl. Nor is -SMe a C₆-C₂₄ alkyl group substituted by any one of the recited substituents. Additionally, Z as claimed must be “a C₁-C₁₀ alkyl group.” See claim 61. The Runquist compound has a fifteen carbon (C₁₅) chain in that position.

For at least those reasons, the Runquist compound does not anticipate the presently pending claims. See claim 61. Therefore, this rejection should be withdrawn.

Rejection over WO 2000/0030444

The Examiner rejected claims 1,87, 88, 94-96 35 U.S.C. § 102(b) as allegedly anticipated by WO 2000/00300444 ("WO '444"). Office Action at 6-7. Applicants respectfully traverse. Here again, Applicants respectfully point out that claim 1 is no longer pending.

The compound disclosed in WO '444 having the formula:



does not anticipate the present claims for at least the reason that there is no "Y," as recited in the instant claims, in either of the two alkenyl chains. In particular, claim 61 recites that "Y is chosen from S, Se, SO₂, and SO." S, Se, SO₂ and SO are entirely absent from the two alkenyl chains of the WO '444 compound. In addition, this compound is not a diacylglycerol as the Examiner stated, but rather a triacylglycerol. Regardless of the correct nomenclature, this compound does not fall within the scope of the presently pending claims. Therefore, this rejection should also be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: January 12, 2010

By: *Erin M. Sommers*
Erin M. Sommers
Reg. No. 60,974